IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

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| MANNATECH, INC. | § | |
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| Plaintiff, | § | |
| | § | |
| VS. | § | NO. 3-06-CV-0471-BD |
| | § | |
| GLYCOBIOTICS INTERNATIONAL, INC. | § | |
| | § | |
| | § | |
| Defendant. | § | |

**MEMORANDUM OPINION AND ORDER**

Plaintiff Mannatech, Inc. has filed suit against Defendant Glycobiotics International, Inc. alleging infringement of U.S. Patent Nos. 6,929,807 ("the '807 Patent") and 7,157,431 ("the '431 Patent"). Both sides now seek construction of the disputed claim terms. Having considered the claim language, the patent specification, the prosecution history, and the other evidence and briefing submitted by the parties, the court issues the following claim construction order.

I.

Plaintiff is the owner by assignment of the '807 Patent, entitled "Compositions of Plant Carbohydrates as Dietary Supplements," which claims a dietary supplement composition of nutritionally effective amounts of "isolated and purified" saccharides for the promotion and maintenance of good health. (*See* Plf. Cl. Const. App. at 6-21). The '431 Patent is a continuation of the '807 Patent and shares a common specification. (*Id.* at 224-39). In this lawsuit, plaintiff alleges that a dietary supplement manufactured and sold by defendant under the brand name "Glycomannan" infringes one or more claims of the '807 and '431 Patents. (*See* Plf. First Am.

Compl. at 4, ¶¶ 20-24 & 6-7, ¶¶ 38-42).[1] Defendant denies any infringement and maintains that the patents in-suit are invalid for a variety of reasons. (Def. Ans. at 3-4, ¶¶ 20-24, 5, ¶¶ 38-42, & 10-11, ¶¶ 1-10).

II.

The threshold issue in any patent infringement case is claim construction. "A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Claim construction is a question of law for the court to decide. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 1387, 134 L.Ed.2d 577 (1996). The words of a claim "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005), *cert. denied*, 126 S.Ct. 1332 (2006), *quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Ordinary and customary meaning is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention[.]" *Id.* at 1313. When the ordinary and customary meaning of a term is not readily apparent, "the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Id.* at 1314, *quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Those sources include the words of the claims themselves, the patent specification, the prosecution history, and extrinsic evidence. *Id.*; *see also Vitronics*, 90 F.3d at 1582.

[1] Plaintiff also sues for: (1) trademark infringement, (*see* Plf. First Am. Compl. at 8-9, ¶¶ 56-63); (2) business disparagement, (*see id.* at 9, ¶¶ 64-70); (3) tortious interference with prospective business relations, (*see id.* at 10, ¶¶ 71-79); (4) tortious interference with existing contracts, (*see id.* at 11, ¶¶ 80-88); and (5) injury to business reputation, (*see id.* at 11-12, ¶¶ 89-95). Those causes of action are not affected by the court's claim construction ruling.

The ordinary meaning of a claim term cannot be determined in a vacuum. *Phillips*, 415 F.3d at 1315; *see also Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005). Rather, patent claims "must be read in view of the specification, of which they are a part." *Phillips*, 415 F.3d at 1315, *quoting Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 116 S.Ct. 1384 (1996). The specification is always highly relevant to the claim construction analysis and, thus, is the primary basis for construing the claims. *Id.* The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication. *Vitronics*, 90 F.3d at 1582. The court also may consider the prosecution history in determining the meaning of disputed claim terms. *Id.* at 1582-83; *see also CVI/Beta Ventures, Inc. v. Tura LP.*, 112 F.3d 1146, 1158 (Fed. Cir. 1997), *cert. denied*, 118 S.Ct. 1039 (1998). The prosecution history contains a complete record of all proceedings before the Patent and Trademark Office ("PTO"), including any express representations made by the applicant regarding the scope of the claims. *Vitronics*, 90 F.3d at 1582. Because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and may be less useful for claim construction purposes. Nonetheless, "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317, *citing Vitronics*, 90 F.3d at 1582-83.

While most patent claims can be construed solely on the basis of intrinsic evidence, extrinsic evidence may be considered "for background and education on the technology implicated by the presented claim construction issues." *Key Pharmaceuticals v. Hercon Laboratories Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998). Extrinsic evidence consists of all evidence external to the patent and the

prosecution history, including expert and inventor testimony, dictionaries, and learned treatises. *Markman*, 52 F.3d at 980; *see also Vitronics*, 90 F.3d at 1583. Although extrinsic evidence is generally less reliable and less probative than intrinsic evidence, it may assist the court in better understanding the underlying technology and the way in which one skilled in the art might use the claim terms. *Phillips*, 415 F.3d at 1318. However, the court must discount any extrinsic evidence "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id*., *quoting Key Pharmaceuticals*, 161 F.3d at 716.

III.

The '807 and '431 Patents describe combinations of various saccharides, or sugars, used as a dietary supplement. (*See* Plf. Cl. Const. App. 6-21, 224-39). In their claim construction briefs, the parties seek construction of the term "isolated and purified," which appears in Claim 1 of the '807 Patent:

> A dietary supplement composition, comprising: nutritionally effective amounts of *isolated and purified* galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(*Id.* at 20) (emphasis added). Similar language is used in Claim 1 of the '431 Patent:

> A dietary supplement composition comprising: a nutritionally effective amount of *isolated and purified* acetylated mannose; and a nutitionally effective amount of at least five *isolated and purified* saccharides selected from: galactose, glucose, mannose, xylose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, iduronic acid and arabinogalactan.

(*Id.* at 238) (emphasis added).[2] Plaintiff asks the court to construe "isolated and purified" to mean "performing one or more steps to exclude unwanted components and provide a nutritionally effective product." (*See* Plf. Cl. Const. Br. at 14). Defendant believes that the term means "obtained alone with other components removed therefrom." (*See* Def. Cl. Const. Br. at 3 & Def. Cl. Const. App. at 67-68). Thus, it appears that the parties generally agree that "isolated and purified," as used in the subject patents, means that the component sugars have been separated from other, unwanted components. However, defendant's proposed claim construction contains a further limitation that requires the isolated sugars to be "obtained alone" with a purity level of at least 95%. (*Id.*). Plaintiff opposes any numerical purity requirement, arguing instead for a broad construction of "isolated and purified" that teaches a process of excluding unwanted components from sugars obtained from both natural and chemical sources. (*See* Plf. Cl. Const. Br. at 14). The court will address the parties' respective arguments in turn.

A.

In support of its proposed claim construction, defendant relies on Example 2 in the specification of the '807 Patent, which reads:

> Another suitable composition for a product according to the present invention is as follows:
>
> 25 kilograms each of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose *available from* Florida Food Products as well as *Aldrich Chemical Company and Sigma Chemical* is charged into a stainless steel ribbon blender and mixed for five (5) minutes. Then 250 grams of Aerosil 380 (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler. The mixture is then

[2] Claim 1 is the sole independent claim of the '807 and '431 Patents. The parties seek the same construction of "isolated and purified" where those terms appear either explicitly or by reference in the dependent claims of the patents-in-suit. *See Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305, 1310 (Fed. Cir. 2001) ("We also construe independent claims consistently with the claims that depend from them.").

> agitated for fifteen (15) minutes. Finally, 100 grams of calcium stearate is added to the mixture as a lubricant and the mixture is agitated for an additional three (3) minutes to generate a bulk powder. The powder is then encapsulated into size #1 gelatin capsules at a fill weight of 250 mg using a Model 8 (Elanco) capsule filling machine.

(Def. Cl. Const. App. at 12) (emphasis added).[3] Defendant focuses on Example 2 because it was cited by counsel for the applicants when challenged by the patent examiner to show support, by way of specific examples in the specification, "of the newly limited genus which would show possession of the concept of a dietary supplement composition comprising a nutritionally effective amount of 'isolated and purified saccharides.'" (*See* Plf. Cl. Const. App. at 181-82, 215). Although nothing in the patent itself or the prosecution history mentions the level of purity of the component sugars, product catalogs published by Aldrich Chemical Company and Sigma Chemical, two of the suppliers mentioned in Example 2, list compounds with a purity level of 95% or greater. (*See* Def. Cl. Const. App. at 58-61, 62-66). Defendant therefore reasons that the phrase "isolated and purified" requires the isolated sugars to be "obtained alone" with a purity level of at least 95%.

The court rejects this selective reading of the claim language. Importing a purity requirement of 95% or more would limit the claim to the specific embodiment disclosed in the written description. The Federal Circuit has cautioned against such an approach to claim construction, "even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.'" *JVW Enterprises, Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005), *citing Phillips*, 415 F.3d at 1323. Here, the patent specification makes clear that the invention includes sugars available from a wide

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[3] Example 2 in the specification of the '431 Patent is identical in all respects. (*Compare* Def. Cl. Const. App. at 12 *with id.* at 28).

variety of natural and synthetic sources, and that "the composition of the invention is not intended to be limited by the source from which the [sugars] are obtained." (*See* Plf. Cl. Const. App. at 15, 232). Specifically, Claim 8 of the '431 Patent states:

> The dietary supplement composition of claim 1, wherein the acetylated mannose is obtained from the group consisting of aloe vera and acetylated polymannose, and the at least five isolated and purified saccharides are obtained from the group consisting of gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

(*Id.* at 239). Table 3 included in both the '807 and '431 Patents lists more than one dozen natural sources of the claimed sugars. (*Id*. at 15, 232). Likewise, Example 1 refers to:

> A suitable composition for a product according to the present invention is as follows: *tragacanth gum* (100 kg), a source of galacturonic acid, galactose, fucose, xylose, arabinose, and rhamnose, is charged into a stainless steel ribbon blender and *guar gum* (10 kg), a source of mannose and galactose, is charged into the stainless steel ribbon blender. The mixture of tragacanth gum and guar gum is mixed for five (5) minutes. Then 250 grams of Aerosil 380 (silica gel) is added to the mixture as a flowing agent and 200 kilograms of *rice flour*, a source of glucose, is added as a gluten-free filler.

(*Id.* at 17, 234) (emphasis added). No specific source of the tragacanth gum, guar gum, or rice flour is mentioned. By contrast, Example 3 lists other suitable ingredients for the invention, including Gum Tragacanth T/3, Gum Ghatti No. 1, arabinogalactin, and MANAPOL, all of which are available from chemical supply companies. (*Id.* at 17-18, 235). Nowhere in the claim language, the specification, or the prosecution history of either patent is there any evidence of an intent to limit the source of sugars to those listed in the Aldrich Chemical and Sigma Chemical catalogs or to require that the sugars be at least 95% pure. *See e.g. RF Delaware, Inc. v. Pacific Keystone*

*Techologies, Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003) ("[W]hen a claim term is expressed in general descriptive words, it typically will not be limited to a numerical range that may appear in the written description as referring to a preferred embodiment or in other, narrower claims."); *Modine Manufacturing Co. v. U.S. International Trade Comm'n*, 75 F.3d 1545, 1557 (Fed. Cir.), *cert. denied*, 116 S.Ct. 2523 (1996) ("Mathematical precision should not be imposed for its own sake."). The court therefore determines that the term "isolated and purified" does not include a numerical purity requirement.

B.

Nor can the court accept plaintiff's proposed construction of "isolated and purified," which requires that the product be "nutritionally effective" and describes a process of excluding unwanted components from the sugars that includes "predigestion to make the saccharides bioavailable to the host." (*See* Plf. Cl. Const. Br. at 14). The "nutritionally effective" requirement is already part of Claim 1, which describes a dietary supplement comprising "nutritionally effective amounts" of isolated and purified sugars. (*See* Plf. Cl. Const. App. at 20, 238). The patent specification defines "nutritionally effective amount" to mean "that amount which will provide a beneficial nutritional effect or response in a mammal." (*Id.* at 16, 233). Because the language of the claim itself requires the invention to be "nutritionally effective," it would be superfluous to impose such a limitation on the definition of "isolated and purified." *See Power Mosfet Technologies, L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004) (interpretations that render some portion of the claim language superfluous are disfavored).

To the extent plaintiff argues that the term "isolated and purified" specifically contemplates a process of "predigestion to make the saccharides bioavailable to the host," such an argument fails

in light of the instrinsic evidence of record. During the prosecution of the '807 Patent, the applicants added the claim that ultimately issued as Claim 1:

> A dietary supplement for providing nutritional product saccharides which saccharides are essential components of glycoproteins in a mammal, said dietary supplement comprising nutritionally effective amounts of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(Plf. Cl. Const. App. at 62-63). However, the PTO rejected this claim as being anticipated by the prior art. (*Id.* at 82). According to the examiner, the prior art taught that "sea urchin embryos comprise the instantly claimed saccharides" and that such embryos can be used as dietary supplements. (*Id.*). In an attempt to overcome this objection, the applicants rewrote the claim with the following limitation:

> A dietary supplement composition comprising nutritionally effective amounts of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose; *wherein said composition is preservative-free and said saccharides are bioavailable as monosaccharides*.

(*Id*. at 97) (emphasis added). The applicants argued that the proposed limitation distinguished their invention from the prior art because the prior art did not "disclose treating the hyaline layer or the sea urchin eggs to make the saccharides bioavailable as monosaccharides." (*Id*. at 100). The PTO responded that the new limitation had no support in the as-filed specification and rejected the insertion of the limitation as a new concept. (*Id.* at 114-15). The examiner specifically noted that "nowhere in the disclosure of Applicant can be found any teaching or suggestion of a treatment of sources of carbohydrates comprising the claimed saccharides to make the saccharides of the claimed invention bioavailable as monosaccharides." (*Id*. at 115).

The applicants made two more attempts to rewrite their claim. First, they deleted the language specifying that the sugars be "bioavailable as monosaccharides," substituting the following limitation:

> A dietary supplement composition comprising nutritionally effective amounts of *predigested forms of* galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(*Id.* at 129) (emphasis added). In support of this new limitation, the applicants relied on expert testimony to establish that "it is the predigestion of the saccharides that makes the saccharides bioavailable as monosaccharides." (*Id*. at 132). The applicants also pointed to their patent application, which described various techniques for accomplishing predigestion. (*Id.*). However, the examiner rejected the proposed claim as indefinite and uncertain. (*Id.* at 141). Finally, the applicants revised their claim to substitute the term "isolated and purified" for "predigested forms" of the component sugars:

> A dietary supplement composition comprising a nutritionally effective amount of *isolated and purified* galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(*Id*. at 161) (emphasis added). Initially, the revised claim was rejected because the "isolated and purified" limitation, like the earlier proposed limitation requiring the sugars to be bioavailable as monosaccharides, had no literal support in the specification, either by way of generic disclosure or specific examples. (*Id.* at 182). The examiner reversed her decision after a telephone interview with an attorney for the applicants, wherein counsel relied on Example 2 to show that the component sugars "would have to be isolated and purified at some point." (*Id.* at 215). The '807 Patent issued shortly after that interview. (*Id.* at 220).

It is clear from the prosecution history of the '807 Patent that the PTO expressly rejected claim language that included a process of "predigestion to make the saccharides bioavailable to the host." Nor is there any intrinsic evidence to suggest that the term "isolated and purified" includes a process of "predigestion."[4] To the extent plaintiff relies on extrinsic evidence to reintroduce the concept of "predigestion" at the claim construction stage, such evidence cannot be used to arrive at a construction of the claim that is clearly contrary to the public record. *See Phillips,* 415 F.3d at 1318; *Vitronics*, 90 F.3d at 1584. Moreover, none of the expert opinions offered by plaintiff support a construction of "isolated and purified" that includes a process of "predigestion to make the saccharides bioavailable to the host."[5] Dr. Bill McAnalley, a pharmacology-toxicology expert and one of the named inventors of the '807 and '431 Patents, interprets the disputed claim term to mean "removed from nature and separated or detached by one or more steps from an unwanted substance or substances." (Plf. Cl. Const. App. at 316). Mark Tengler, the president of a Texas-based company that specializes in manufacturing nutracuetical and pharmaceutical products, states that "isolated and purified" means "removed from nature and then (or thus) separated or detached from unwanted components by human intervention." (*Id.* at 368, ¶ 3 & 370, ¶ 11). Dr. Garold S. Yost,

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[4] The prosecution history of the '431 Patent reveals that the applicants participated in a personal interview with the patent examiner on February 27, 2006, six months after the '807 Patent was issued. During that interview, the applicants proposed an amendment to narrow the scope of several dependent claims, clarifying that "the isolated and purified acetylated mannose and the isolated and purified saccharides are obtained in nutritionally effective amounts by *digestion* from the sources listed in claim 28 and paragraphs [0031], [0033], [0042], [0043] and [0046] of the present application." (Plf. Cl. Const. App. at 293) (emphasis added). The PTO never responded to the proposed amendment and the prosecution history contains no further discussion of the interview between the applicants and the examiner. This lone reference to "digestion" is simply too vague to support plaintiff's argument that "isolated and purified" includes a process of "predigestion to make the saccharides bioavailable to the host."

[5] Defendant has filed a motion to strike the testimony of plaintiff's experts on the ground that their reliance on extrinsic evidence, rather than intrinsic evidence, is contrary to the hierarchy of analysis established in *Phillips*. The court has not relied on any of this testimony in construing the disputed claim terms, other than to show that the experts do not support the construction proposed by plaintiff. Consequently, the motion to strike is denied as moot. *See Consortium Information Services, Inc. v. National Information Services, Inc.*, No. 3-99-CV-2509-BD, 2001 WL 1516758 at *3 n.5 (N.D. Tex. Nov. 21, 2001) (Kaplan, J.) (overruling as moot objections to affidavits where none of the evidence was necessary to the disposition of pending motion).

a Professor of Pharmacology and Toxicology at the University of Utah who has conducted numerous studies on herbal supplements, opines that the disputed term means "performing one or more steps to exclude unwanted components from a natural source, while providing a nutritionally effective product." (*Id*. at 376-77, ¶¶ 3-4 & 378, ¶ 11). Because there is no evidence that the phrase "isolated and purified" includes a process of "predigestion," the court declines to construe the claim in such a manner.

**CONCLUSION**

For these reasons, the court construes the term "isolated and purified," as used in the '807 and '431 Patents, to mean "separated from other, unwanted substances."

SO ORDERED.

DATED: June 26, 2007.

JEFF KAPLAN
UNITED STATES MAGISTRATE JUDGE